LICENSING AND ENFORCEMENT DIVISION

PUBLIC cGMP INSPECTION REPORT OF PHARMACEUTICAL MANUFACTURER:

Name of company: **Senador Laboratories (Pvt) Ltd**

1.0 General information

1.1 Name of Inspected company	**Senador Laboratories (Pvt). Ltd**
1.2 Physical address	Plot 1606 – 1609, G.I.D.C, Sarigam, Tal: Umergam, Dist. Valsad, 396155, Gujarat, India
1.3 Corporate address	Plot No.2B and 2C, Biotech park phase II, Lalgadi Malakpet, Medchal Malkajgiri, Hyderabad, Telangana, India,500101
1.4 Summary of the main activities performed	Manufacture of the following finished pharmaceutical dosage forms: Hormonal oral tablets, General oral tablets (placebo & Iron Fumarate) tablets,
1.5 Scope of Inspection	Product based inspection to verify compliance with cGMP guidelines for the manufacture of Hormonal oral tablets, General oral tablets (placebo & Iron Fumarate) tablets
1.6 Purpose of Inspection	To ascertain cGMP compliance to support registered products in Zimbabwe
1.7 Inspectors	Ms Martha Mwatseteza - **Co-inspector** Mr. Sly Mutyavaviri **–Lead-inspector**
1.8 Date of Inspection	10th – 11th of February, 2025

2.0 Abbreviations list

Abbreviation	Full Form
AHU	Air Handling Unit
CAPA	Corrective and Preventive Action
DPML	Direction de la Pharmacie, du Médicament et des Laboratoires (Ivory Coast)
EM	Environmental Monitoring
FDA	Food and Drug Administration
FTIR	Fourier Transform Infrared Spectroscopy
GC	Gas Chromatography
HPLC	High-Performance Liquid Chromatography
HVAC	Heating, Ventilation, and Air Conditioning
LAF	Laminar Air Flow
MAL	Material Air Lock
MCAZ	Medicines Control Authority of Zimbabwe
MOH	Ministry of Health
NDA	National Drug Authority (Uganda)
NVPC	Non-Viable Particle Count
OOS	Out of Specification
PAL	Personnel Air Lock
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PQR	Product Quality Review
PW	Purified Water
QA	Quality Assurance
QC	Quality Control
RLAF	Reverse Laminar Air Flow
SOP	Standard Operating Procedure
TRS	Technical Report Series
WFI	Water for Injection
WHO	World Health Organization
cGMP	Current Good Manufacturing Practice

3.0 Summary

3.1 Brief summary about the facility

Senador Laboratories (Pvt) Ltd is located at Plot 1606 – 1609, G.I.D.C, Sarigam, Tal: Umergam, Dist. Valsad, 396155, Gujarat, India. The company manufactures Hormonal oral tablets and general oral tablets (placebo & Iron Fumarate) tablets.

The Medicines Control Authority of Zimbabwe (MCAZ) Inspectorate audited the blocks manufacturing hormonal tablets and general oral tablets. The audit was conducted from the 10th to the 11th of February 2025. The company had been audited by other regulatory bodies.

3.2 General Information about the Company and the Site

This was a routine inspection of the site by the Medicines Control Authority of Zimbabwe (MCAZ) Inspectorate, to support registered products in Zimbabwe. The inspection was product-based and focused on the products that were intended for the Zimbabwean market, as provided below:

Product	Dosage form	Registration number
Control -L- Levonogestrel ethinylestradiol; ferrous fumarate; 0.15; 0.03; 75mg tablet	Tablet	2014/21.2.1/4923

The first day activities comprised introductory meeting in which the MCAZ Inspectorate and the Senador Laboratories team introduced themselves. This was followed by a projected Senador Company power-point presentation. Thereafter the scope of the inspection was defined, both parties agreed on the blocks to be inspected. Immediately after, extensive document review commenced. Later in the day a walk-through inspection was conducted, for the raw material warehouse and the production block for the OCP and General tablet section.

Second day activities encompassed further document review and the inspection of the Quality control laboratories chemistry section and the microbiology section, and the utilities blocks (Water Purification and HVAC system). The inspectors then held an inspectors' meeting in which findings from the inspection were discussed and there was consensus on the inspection findings.

The inspection was conducted with reference to and in accordance with the WHO Good Manufacturing Practices detailed in the Technical Report Series 986, Annex 2 of 2014, among other current relevant guidelines. The inspection was conducted in an open and cooperative atmosphere.

3.3 Areas inspected

- **Quality Management**: Product Quality Review (PQR), Quality Risk Management, Deviation control, finished product and starting material batch release, Contract

agreements and Supplier approval.

- **Materials Management**: Receipt, handling, quarantine, sampling, release, reject, temperature (and humidity) monitoring and dispensing.
- **Good Practices in Production**: Production areas, production equipment, documentation and instructions, sanitation cleaning and maintenance, batch records, calibration, contamination control, in process controls.
- **Quality Control**: Review of test procedures and specifications.
- **Utilities**: HVAC, Purified Water,
- **Environmental Monitoring**: EM Programme
- **Equipment qualification** and preventive maintenance

3.4 Utilities

a. Water Purification system
b. HVAC system
c. Compressed air system

3.5 Documents reviewed

As listed in final inspection report.

4.0 System Summaries

Pharmaceutical Quality System.
Product Quality review (PQR)
The SOP of PQRs was submitted for review. Examples of PQRs were submitted for review. These were executed according to the set procedure.

Complaints

The SOP for complaints handling was submitted for review. The log of complaints was submitted and examples of complaints were submitted for review. These were being drafted in accordance with the SOP.

Deviations

The SOP for handling deviations was submitted for review. The log of deviations was submitted for review. Examples of deviations were submitted for review and these were being handled according to the SOP.

Change Control

The SOP for handling of changes was submitted for review. The log of changes was submitted

for review. The approach to handling of changes was in line with the SOP.

Vendor Qualification

The SOP for handling vendor qualifications was submitted for review. There was provision of an approved vendor list. The qualification reports for the vendors were reviewed and these were acceptable.

Stability Studies

SOP for the management of the stability programme was submitted for review. he stability chambers were inspected. The climatic conditions for zone IVb were being monitored. There was no deviation to the stability program.

OOS handling

The SOP for OOS handling was submitted for review. The OOS were being investigated in line with the SOP.

Quality Control tour

The laboratory was inspected. Key equipment such as HPLCs, GCs, Karl Fishcer and balances with printing capabilities, FITRs, Dissolution chambers, UVVIS, and Friability testers were available.

HPLC

The SOP for operation of the HPLCs was submitted for review. The SOPs for audit trail review was submitted for review. the HPLCs were being calibrated according to the set calendar.

Dissolution testing apparatus

The SOP for operation and calibration of the dissolution apparatus was submitted for review. The geometric means and the co-efficiency of variation were verified and were acceptable.

FTIR

The SOP for operation of the FTIR was submitted for review. These were being adequately handled.

Validations and qualification

Environmental monitoring

SOP for Environmental monitoring was submitted for review. The approach to passive and active air sampling was specified in the SOP.

Dust Extraction System

The PQ for the dust extraction system was submitted for review. Periodic performance qualification protocol of HVAC were submitted for review. The critical parameters had been considered.

Hold time studies

The SOP for hold time studies was submitted for review. Protocols for hold time studies for the products under the scope of the inspection were presented for review. The hold time studies were indicated in the BMRs.

AHU qualification and preventative maintenance

The approach to AHU qualifications was specified. The critical process parameters were considered. The AHUs were being adequately qualified.

Cleaning Validation

The SOP for cleaning validation was submitted for review. The verification protocols were verified. The validations had been executed according to the

Utilities
Purified water system

The P and ID diagram for the water system was submitted for review. The approach to generation, purification, distribution and monitoring was verified. The annual trend reports were reviewed and were acceptable.

Facility tour

The facility was inspected. The warehouse was inspected. The dispensary area was inspected and was in a good state of maintenance. The dry mixing area was inspected**.** The compression area was inspected. The coating area was inspected. The ferrous fumarate area was inspected. The tooling area was inspected and the punch sets handling procedures were submitted for review.

Primary packaging areas

The primary packing and the secondary packing areas were inspected an these were in a good state of maintenance.

Containment Studies

The containment studies were submitted for review. The critical components had been considered.

Utilities
Air handling units (AHU)

The AHUs were inspected. The approach to filter handling and changing was specified.

Maintenance

The SOP for preventative maintenance was submitted for review. The schedules were reviewed and these were satisfactory.

4.0 Conclusion

Based on the areas inspected, the people met, and the documents reviewed including the observations listed in the Inspection Report **Senador Laboratories (Pvt) Ltd** located at **Plot 1606 – 1609, G.I.D.C, Sarigam, Tal: Umergam, Dist. Valsad, 396155, Gujarat, India** was considered to be operating at an acceptable level of compliance with WHO TRS cGMP guidelines for the manufacture of hormonal and general oral dosage forms (tablets)**.**

All the non compliances observed during the inspection those listed in the full report were addressed by the manufacturer to a satisfactory level prior to the publication of the MCAZ PIR

The site will be reinspected **4 years** from the date of the last inspection in line with the risk based reinspection frequency determination.

5.0 References

1. WHO good manufacturing practices for pharmaceutical products: main principles. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Eight Report* Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2 http://www.who.int/medicines/publications/pharmprep/en/index.html
2. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-six Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 1033), Annex 2 https://www.who.int/publications/m/item/annex-3-trs-1033
3. WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8, https://www.who.int/publications/m/item/Annex-8-trs-1010
4. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3 https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1019-annex3-gmp-validation.pdf?sfvrsn=9440a5c_0&download=true
5. Supplementary guidelines on good manufacturing practices: validation. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report*. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4 http://www.who.int/medicines/publications/pharmprep/en/index.html
6. WHO good practices for pharmaceutical microbiology laboratories. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report*. Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2 http://www.who.int/medicines/publications/pharmprep/en/index.html
7. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. *WHO Expert Committee on specifications for pharmaceutical preparations*. *Forty-third report.* Geneva, World Health Organization, 2009. (WHO Technical Report Series, No. 953), Annex 2 http://www.who.int/medicines/publications/pharmprep/en/index.html
8. WHO guidelines on quality risk management. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report* Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2 http://www.who.int/medicines/publications/pharmprep/en/index.html

9. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty Ninth Report* Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 3
http://www.who.int/medicines/publications/pharmprep/en/index.html

10. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty Ninth Report* Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4
http://www.who.int/medicines/publications/pharmprep/en/index.html